Petition

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date appearing below.
ELI LILLY AND COMPANY

By Linda M. Dunbar Date June 30, 1999

#15

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: United States Patent No. 4,418,068

Patentee	:	Charles D. Jones	Attn: Box Patent Ext.
Assignee	:	Eli Lilly and Company	Attorney Docket: X-5526A
Issue Date	:	November 29, 1983	

STATUS LETTER

Assistants Commissioner for Patents
Washington, D. C. 20231
Sir:

Applicants mailed a Request for Extension of Patent Term Under 35 U.S.C. 156, with accompanying Letter of Transmittal, on January 20, 1998. Attached is a copy of the post card received from the Patent and Trademark Office related thereto. Applicants then sent in a Status Letter on January 29, 1999 requesting the status of this Patent. Also attached are copies of the Status Letter and the post card received from the Patent Office in connection with the Status Letter. On May 11, 1999, Applicants' Administrative Assistant spoke with Ms. Karen Tyson of the United States Patent & Trademark Office. Ms. Tyson indicated she was unable to locate the Request for Extension of Patent Term. Applicants then faxed to Ms. Tyson a copy of such Request for Extension. A copy of the facsimile sent on May 11, 1999 is attached.

Applicants have received no further communication from the Patent and Trademark Office regarding the status of the Request for Extension of Patent Term Under 35 U.S.C. 156. It would be appreciated if the Office would advise applicants of the current status of the Request for Extension of Patent Term Under 35 U.S.C. 156.

Respectfully submitted,

James J. Sales
Attorney for Applicants
Registration No. 33,773
Phone: 317-276-3474

Eli Lilly and Company
Patent Division/JJS
Lilly Corporate Center
Indianapolis, Indiana 46285

June 29, 1999

Lilly

Eli Lilly and Company
Patent Division

Lilly Corporate Center
Indianapolis, Indiana 46285 U.S.A.

Cable Address: LILLYINTER
Telex: 276051 ELI LILLY IND A
Telecopier: (317) 276-1294

Telephone: (317) 276-2480

VIA UPS

May 11, 1999

Ms. Karen Tyson
Assistant Commissioner of Patents
United States Patent & Trademark Office
Box Patent Extension
Washington, DC 20231

RE: U.S. Patent Number 4,418,068
Issued: 11-29-83
Our Reference: X-5526A

Dear Ms. Tyson:

Per our conversation of today's date, enclosed please find a complete copy of the Request for Extension of Patent Term which we filed with the USPTO on January 20, 1998. I have also included a copy of the post-card which has been stamped by your office as having been received.

If you need anything further, please do not hesitate to contact me.

Very truly yours,

Linda S. Earl

Linda S. Earl
Administrative Assistant to James J. Sales

:lse
Enclosures

PATENT

Dkt. No. K-5526A Atty JJS

RECEIVED BY THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Patent NO. issued

~~Serial No.~~ 4,418,068 OR ~~Filed~~: 11-29-83

Applicants: Jones

Interference No. _____

Parties: _____

_____

Response _____

IDS/1449 _____

Notice of Appeal _____

Letter Trans./Brief _____

Affirm 821/Diskette _____

Trans./Decl. Power Atty _____

Amendment/Response _____

Assignment/Cover Sheet _____

Issue Fee _____

Express Abandonment _____

Fee Authorization _____

Communication _____

Other Papers:

Status Letter

Certificate of Mailing

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date appearing below.
ELI LILLY AND COMPANY

By Linda M. Dunbar Date January 29, 1999

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: United States Patent No. 4,418,068

Patentee : Charles D. Jones

Assignee : Eli Lilly and Company

Issue Date : November 29, 1983

Attn: Box Patent Ext.

Attorney Docket: X-5526A

STATUS LETTER

Assistants Commissioner for Patents
Washington, D. C. 20231
Sir:

Applicants mailed a Request for Extension of Patent Term Under 35 U.S.C. 156, with accompanying Letter of Transmittal, on January 20, 1998. Attached is a copy of the post card received from the Patent and Trademark Office related thereto.

Applicants have received no further communication from the Patent and Trademark Office regarding this Request for Extension of Patent Term Under 35 U.S.C. 156. It would be appreciated if the Office would advise applicants of the current status of the Request for Extension of Patent Term Under 35 U.S.C. 156.

Respectfully submitted,

James J. Sales
Attorney for Applicants
Registration No. 33,773
Phone: 317-276-3474

Eli Lilly and Company
Patent Division/JJS
Lilly Corporate Center
Indianapolis, Indiana 46285
January 29, 1999

PATENT

Dkt. No. L 552A Atty GJ

RECEIVED BY THE UNITED STATES
PATENT AND TRADEMARK OFFICE

~~Serial~~ Patent No. 4,418,068 OR Interference No. _____

~~Filed~~ Issued: 11-29-83 Parties: _____

Applicants: Jones _____

Response _____	Amendment/Response _____
IDS/1449 _____	Assignment/Cover Sheet _____
Notice of Appeal _____	Issue Fee _____
Letter Trans./Brief _____	Express Abandonment _____
Affirm 821/Diskette _____	Fee Authorization _____
Trans./Decl. Power Atty _____	Communication _____

Other Papers:

Request for Extension + Letter transmitting Request for Extension

~~Certificate of Mailing~~ Express Mail EM538329863US

"Express Mail" mailing label number EM538329863US
Date of Deposit January 20, 1998
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231..

Gilbert T. Voy
Printed Name

Gilbert T. Voy
Signature

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent No. 4,418,068

Patentee : Charles D. Jones — Attn: Box Patent Ext.

Assignee : Eli Lilly and Company — Attorney Docket: X-5526A

Issue Date : November 29, 1983

LETTER OF TRANSMITTAL OF REQUEST FOR EXTENSION OF PATENT TERM

Assistant Commissioner for Patents
Washington, D.C. 20231
Sir:

Transmitted herewith for filing is a request for extension of term of U.S. Patent No. 4,418,068 and a duplicate thereof, certified as such.

Please charge the filing fee of $1,120 to deposit account No. 05-0840 in the name of Eli Lilly and Company. An original and two copies of this paper are enclosed. The Assistant Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to account No. 05-0840.

The request transmitted herewith has been executed by the undersigned agent of the owner of record of the subject patent. Therefore, the present request is complete and entitled to a filing date of January 20, 1998, as indicated by the Certificate of Mailing by "Express Mail".

ELI LILLY AND COMPANY

By: _____
James J. Sales
Associate General Patent Counsel
Registration No. 33,773
Phone: 317-276-3474

Eli Lilly and Company
Patent Division/JJS
Lilly Corporate Center
Indianapolis, Indiana 46285

January 20, 1998

EM538329863US

"Express Mail" mailing label number EM538329863US

Date of Deposit January 20, 1998

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231..

Gilbert T. Voy — Gil T Voy
Printed Name — Signature

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent No. 4,418,068
Patentee : Charles D. Jones Attn: Box Patent Ext.
Assignee : Eli Lilly and Company
Issue Date : November 29, 1983

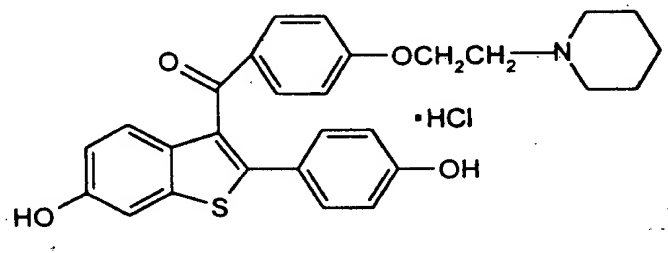
REQUEST FOR EXTENSION OF
PATENT TERM UNDER 35 U.S.C. 156

Assistant Commissioner for Patents
Washington, D.C. 20231
Sir:

Pursuant to Section 201(a) of the Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. 156, Eli Lilly and Company, owner of the above-identified patent by an Assignment recorded on August 5, 1983, in Reel 4152, Frame 627, hereby requests an extension of the patent term of U.S. Patent No. 4,418,068. The following information is submitted in accordance with 35 U.S.C. 156(d) and 37 C.F.R. 1.710 *et seq.* and follows the numerical format set forth in 37 C.F.R. 1.740(a):

(1) A complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics:

The approved product is raloxifene hydrochloride which has the chemical name [6-hydroxy-2-(4-hydroxyphenyl)benzo[b]thien-3-yl]{4 [2-(1-piperidinyl)ethoxy]phenyl}methanone hydrochloride and has the following structure:



Raloxifene hydrochloride is the active ingredient in the product Evista® as may be seen from attached Exhibit A, which is the Product Information sheet for this product.

(2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred:

The regulatory review occurred under Section 505 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.* Section 505 provides for the submission and approval of new drug applications (NDAs) for human drug products meeting the definition of "new drug" under Section 201(p) of the Act.

(3) An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred:

Raloxifene hydrochloride was approved by the Food and Drug Administration (FDA) for commercial marketing pursuant to Section 505 of the FFDCA on December 9, 1997.

(4) In the case of a drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial

marketing or use (either alone or in combination with other active ingredients), the use for which it was approved, and the provision of law under which it was approved.

As stated in Sections 1, 2, and 3 above, the active ingredient in the product Evista® is raloxifene hydrochloride. Raloxifene hydrochloride had not previously been approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act until December 9, 1997.

(5) A statement that the application is being submitted within the sixty day period permitted for submission pursuant to §1.720(f) and an identification of the date of the last day on which the application could be submitted:

The product was approved on December 9, 1997 and the last day within the sixty day period permitted for submission of a request for extension of a patent is February 7, 1998. Since February 7, 1998 is a Saturday, the application may be timely filed on February 9, 1998, the next succeeding business day in accordance with 35 U.S.C. 21. As evident from the Certificate of Mailing by "Express Mail" pursuant to 37 C.F.R. 1.10, this application is timely filed.

(6) A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration:

U.S. Patent No.: 4,418,068
Inventor: Charles D. Jones
Issued: November 29, 1983
Expires: April 3, 2001

(7) A copy of the patent for which an extension is being sought, including the entire specification (including claims) and drawings:

A copy of the patent is attached as Exhibit B.

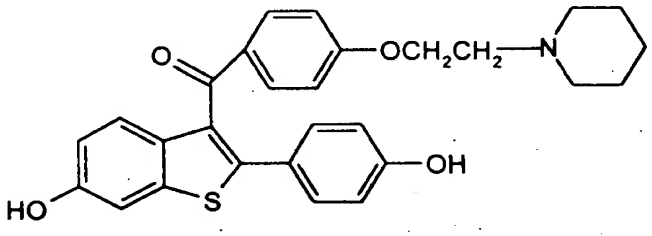
(8) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent:

A copy of the Certificate of Correction is attached as Exhibit C.

Copies of the receipts of maintenance fee payments are attached as Exhibit D.

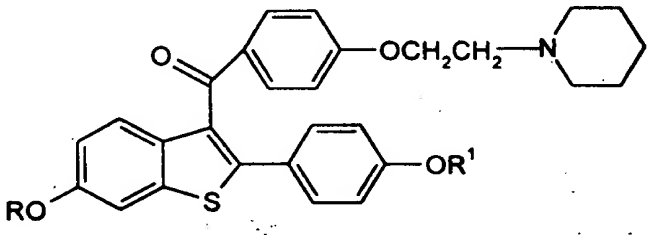
(9) A statement that the patent claims the approved product or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which each applicable patent claim reads on the approved product or a method of using or manufacturing the approved product:

The patent claims the approved product, which is [6-hydroxy-2-(4-hydroxyphenyl)benzo[b]thien-3-yl]{4-[2-(1-piperidinyl)ethoxy]phenyl}methanone hydrochloride. Claim 1 of the patent claims a "compound of the formula



a physiological acceptable ester or ether thereof, or a physiologically acceptable acid addition salt thereof." As this is the structure of raloxifene, claim 1 reads upon the approved product.

Claim 2 of the patent claims a "compound of claim 1 of the formula



wherein R and R^1 independently are hydrogen, $-COR^2$ or R^3;
R^2 is hydrogen, C_1-C_{14} alkyl, C_1-C_3 chloroalkyl, C_1-C_3 fluoroalkyl, C_5-C_7 cycloalkyl, C_1-C_4 alkoxy, phenyl, or phenyl mono- or disubsubstituted with C_1-C_4 alkyl, C_1-C_4 alkoxy, hydroxy, nitro, chloro, fluoro, or tri(chloro or fluoro)methyl;
R^3 is C_1-C_4 alkyl, C_5-C_7 cycloalkyl or benzyl; or a physiologically acceptable acid addition salt thereof."

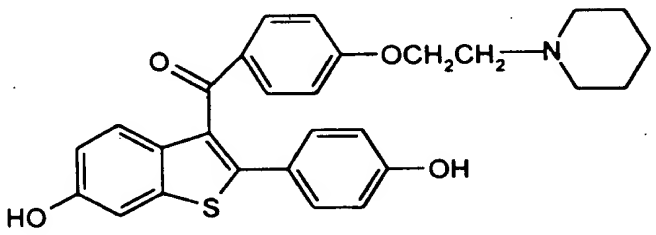
Raloxifene is that compound where R and R^1 are each hydrogen, therefore, claim 2 reads upon the approved product.

Claim 3 of the patent claims the "compound of claim 2 which is 6-hydroxy-2-(4-hydroxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]benzo[b]thiophene, or a physiologically acceptable acid addition salt thereof." 6-Hydroxy-2-(4-hydroxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]benzo[b]thiophene is raloxifene, thus, claim 3 reads upon the approved product.

Claim 5 of the patent claims a "compound of claim 2 wherein one of R and R^1 is hydrogen." Raloxifene is that compound where R and R^1 are each hydrogen, therefore, claim 5 reads upon the approved product.

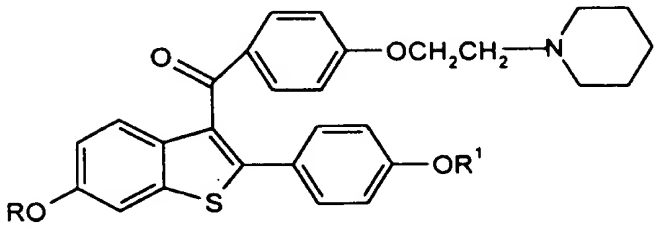
The approved product is in the form of a hydrochloride salt, which is identified at column 6, line 60, of the patent as a preferred pharmaceutically acceptable acid addition salt. Claim 18 of the patent claims a "compound of any one of claims 1 - 7 which is a physiological acceptable acid addition salt." Claim 19 of the patent claims a "compound of any one of claims 1 - 7 which is a hydrochloride." Therefore, the approved product is embraced by claims 18 and 19.

Claim 24 of the patent claims an "antiestrogenic and antiandrogenic pharmaceutical composition comprising a pharmaceutically acceptable diluent and an effective amount of a compound of the formula



a physiological acceptable ester or ether thereof, or a physiologically acceptable acid addition salt thereof." As this is the structure of raloxifene, claim 24 reads upon the approved product.

Claim 25 of the patent claims a "composition of claim 24 wherein the compound is of the formula



wherein R and R^1 independently are hydrogen, $-COR^2$ or R^3;
R^2 is hydrogen, C_1-C_{14} alkyl, C_1-C_3 chloroalkyl, C_1-C_3 fluoroalkyl, C_5-C_7 cycloalkyl, C_1-C_4 alkoxy, phenyl, or phenyl mono- or disubsubstituted with C_1-C_4 alkyl, C_1-C_4 alkoxy, hydroxy, nitro, chloro, fluoro, or tri(chloro or fluoro)methyl;
R^3 is C_1-C_4 alkyl, C_5-C_7 cycloalkyl or benzyl; or a physiologically acceptable acid addition salt thereof." Raloxifene is that compound where R and R^1 are each hydrogen, therefore, claim 25 reads upon the approved product.

Claim 26 of the patent claims a "composition of claim 25 wherein the compound is 6-hydroxy-2-(4-hydroxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]benzo[b]thiophene, or a physiologically acceptable acid addition salt thereof." 6-Hydroxy-2-(4-hydroxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]benzo[b]thiophene is raloxifene, thus, claim 26 reads upon the approved product.

As stated above, the approved product is in the form of a hydrochloride salt. Claim 27 of the patent claims a "composition of claim 26 wherein the compound is the hydrochloride." Therefore, the approved product is embraced by claim 27.

Claim 38 of the patent claims a "composition of claim 25 wherein one of R and R^1 is hydrogen." Raloxifene is that compound where R and R^1 are each hydrogen, therefore, claim 38 reads upon the approved product.

Accordingly, claims 1, 2, 3, 5, 18, 19, 24, 25, 26, 27, and 38 all read on the approved product.

(10) A statement, beginning on a new page, of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows:

(i) For a patent claiming a human drug, antibiotic, or human biological product, the effective date of the investigational new drug (IND) application and the IND number; the date on which a new drug application (NDA) or a Product License Application (PLA) was initially submitted and the NDA or PLA number and the date on which the NDA was approved or the Product License issued;

(ii) For a patent claiming a new animal drug, the date a major health or environmental effects test on the drug was initiated and any available substantiation of that date or the date of an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act became effective for such animal drug; the date on which a new animal drug application (NADA) was initially submitted and the NADA number; and the date on which the NADA was approved;

(iii) For a patent claiming a veterinary biological product, the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective; the date an application for a license was submitted under the Virus-Serum-Toxin Act; and the date the license issued;

(iv) For a patent claiming a food or color additive, the date a major health or environmental effects test on the additive was initiated and any available substantiation of that date; the date on which a petition for product approval under the Federal Food, Drug, and Cosmetic Act was initially submitted and the petition number; and the date on which the FDA published the Federal Register notice listing the additive for use;

(v) For a patent claiming a medical device, the effective date of the investigational device exemption (IDE) and the IDE number, if applicable, or the date on which the applicant began the first clinical investigation involving the device if no IDE was submitted and any available

substantiation of that date; the date on which the application for product approval or notice of completion of a product development protocol under section 515 of the Federal Food, Drug, and Cosmetic Act was initially submitted and the number of the application or protocol; and the date on which the application was approved or the protocol declared to be completed:

On April 26, 1992, Eli Lilly and Company, the assignee of U.S. Patent No. 4,418,068, submitted to the FDA a "Notice of Claimed Investigational Exemption for a New Drug" (IND) under Section 505(i) of the FFDCA to permit the interstate shipment of raloxifene hydrochloride for the purpose of conducting clinical studies to support the approval of a subsequent NDA for raloxifene hydrochloride. A copy of the letter transmitting the IND to the FDA is attached as Exhibit E. By letter dated May 1, 1992, the FDA acknowledged receipt of the IND, assigned the IND number 39503, and indicated that the IND would become effective thirty days after the date of its receipt on April 27, 1992. A copy of this letter is attached as Exhibit F. This establishes the beginning of the "regulatory review period" under 35 U.S.C. 156(g)(1) as May 27, 1992, the effective date of an exemption under Section 505(i).

Lilly submitted a NDA pre-submission for raloxifene hydrochloride on March 13, 1997. This NDA pre-submission contained chemistry, manufacturing and control data and non-clinical pharmacology and toxicology data. This pre-submission did not include the entire NDA, so it did not start the statutory period for regulatory review. A copy of the letter submitting the NDA pre-submission is enclosed as Exhibit G. The NDA pre-submission was received by the FDA on March 17, 1997. A copy of the receipt letter dated March 17, 1997, for the NDA pre-submission from the FDA is included as Exhibit H.

Lilly submitted an NDA for raloxifene hydrochloride, NDA 20815, on June 8, 1997. A copy of the letter transmitting the NDA is attached as Exhibit I. The NDA submission was received by the FDA on June 9, 1997 as indicated by Exhibit J. Thus, for the purpose of the "regulatory review period" under 35 U.S.C. 156(g)(1), June 9, 1997 is the date of initial submission of a new drug application under Section 505 for raloxifene hydrochloride.

The NDA described above was approved on December 9, 1997. Attached as Exhibit K is a letter dated December 9, 1997 from the FDA to Lilly approving the NDA for raloxifene hydrochloride. Thus, for the purpose of the "regulatory

review period" under 35 U.S.C. 156(g)(1), December 9, 1997 is the date of approval of the application for raloxifene hydrochloride submitted on June 8, 1997.

(11) A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities:

During the applicable regulatory review period, Lilly was actively involved in obtaining NDA approval for raloxifene hydrochloride. As discussed in (10) above, the IND for raloxifene hydrochloride was submitted on April 26, 1992, the NDA was submitted on June 8, 1997, and the NDA was approved on December 9, 1997. Lilly was in close consultation with the FDA during the clinical studies conducted under the IND. Similarly, subsequent to the submission of the NDA, Lilly had numerous contacts and meetings with the FDA with respect to the approval and, in fact, conducted additional studies at FDA's request to support the NDA approval. The description of significant activities undertaken by Lilly with respect to raloxifene hydrochloride during the regulatory review period as set forth in Exhibit L is illustrative of the activities involved.

(12) A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of extension claimed, including how the length of extension was determined:

(a) Statement of eligibility of the patent for extension under 35 U.S.C. 156(a):

Section 156(a) provides, in relevant part, that the term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended if (1) the term of the patent has not expired before an application for extension is submitted, (2) the term of the patent has never been extended, (3) the application for extension is submitted by the owner of record of the patent or its agent in accordance with 35 U.S.C. 156(d), (4) the product has been subject to a regulatory review period before its commercial marketing or use, and (5) the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.

As described below by corresponding number, each of these elements is satisfied here:

(1) The term of U.S. Patent No. 4,418,068 expires on April 3, 2001. This application has, therefore, been submitted before the expiration of the patent term.

(2) The term of this patent has never been extended.

(3) This application is submitted by the owner of record, Eli Lilly and Company (Assignment recorded on August 5, 1983, in Reel 4152, Frame 627). This application is submitted in accordance with 35 U.S.C. 156(d) in that it is submitted within the sixty day period beginning on the date, December 9, 1997, the product received permission for marketing under the FFDCA and contains the information required under 35 U.S.C. 156(d).

(4) As evidenced by the December 9, 1997 letter from the FDA (Exhibit K), the product was subject to a regulatory review period under Section 505 of the FFDCA before its commercial marketing or use.

(5) Finally, the permission for the commercial marketing of raloxifene hydrochloride after regulatory review under Section 505 is the first permitted commercial marketing of raloxifene hydrochloride. This is confirmed by the absence

of any approved new drug application for raloxifene hydrochloride prior to December 9, 1997.

(b) Statement as to length of extension claimed:

The term of U.S. Patent No. 4,418,068 should be extended by 1103 days to April 10, 2004. This extension was determined on the following basis: as set forth in 35 U.S.C. 156(g)(1) and 37 C.F.R. 1.775(c), the regulatory review period equals the length of time between the effective date of the initial IND May 27, 1992 and the initial submission of the NDA June 9, 1997, a period of 1839 days, plus the length of time between the initial submission of the NDA June 9, 1997 to NDA approval December 9, 1997, a period of 183 days. These two periods added together equal 2022 days.

Pursuant to 35 U.S.C. 156(c) and 37 C.F.R. 1.775 (d)(1)(i), the term of the patent eligible for extension shall be extended by the time equal to the regulatory review period which occurs after the date the patent was issued. In this case, the patent issued before the effective filing date of the IND, and therefore the regulatory review period is 2022 days as calculated above.

As discussed in paragraph (11) above and as illustrated in Exhibit L, Lilly was continuously and diligently working toward securing NDA approval for raloxifene hydrochloride. As Lilly acted with due diligence during the entire period of regulatory review, the 2022 day period calculated above as the term of the patent eligible for extension should not be reduced for lack of diligence under 35 U.S.C. 156(c)(1) or 37 C.F.R. 1.775 (d)(1)(ii).

Pursuant to 35 U.S.C. 156(c)(2) and 37 C.F.R. 1.775 (d)(1)(iii), this 2022 day period is to be reduced by one half of the time from the effective date of the initial IND May 27, 1992, or the date of patent issue, November 29, 1983, whichever is later, to the date of initial submission of the NDA, June 9, 1997, a period of 1839 days. One half of this period is 919 days. Thus, the 2022 day period is reduced by 919 days leaving a revised regulatory period of 1103 days.

Pursuant to 35 U.S.C. 156(c)(3) and 37 C.F.R. 1.775(d)(2-4), if the period remaining in the term of the patent after the date of approval December 9, 1997 to April 3,

2001, (a period of 1211 days), when added to the revised regulatory review period (1103 days) exceeds 14 years (5113 days), the period of extension must be reduced so that the total of both such periods does not exceed fourteen years. In this case, the total of both such periods does not exceed 14 years and, therefore, the 1103 day revised regulatory review period is not reduced.

The period of patent term extension as calculated above is also subject to the provisions of 35 U.S.C. 156(g)(4) and 37 C.F.R. 1.775(d)(5-6). The patent to be extended issued before and clinical evaluation of the approved product began after the enactment of the statute, September 24, 1984. Since commercial marketing of the drug was approved after enactment of the statute, the five year maximum on extension as provided in 35 U.S.C. 156(g)(6)(B) and 37 C.F.R. 1.775(d)(6) is applicable. In this case, the five year maximum exceeds the revised regulatory period, thus, the term of the patent is eligible for a 1103 day extension until April 10, 2004.

(13) A statement that applicant acknowledges a duty to disclose to the Assistant Commissioner for Patents and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought (See §1.765):

Applicant acknowledges a duty to disclose to the Assistant Commissioner for Patents and the Secretary of Health and Human Services any information which is material to any determination of entitlement to the extension sought. Further to the information already presented in this application and attached exhibits, applicant notes that on June 18, 1982, Eli Lilly and Company, the assignee of U.S. Patent No. 4,418,068, submitted to the FDA an IND for the purpose of conducting clinical studies to support the use of raloxifene hydrochloride as an antiestrogen agent. By letter dated June 21, 1982, the FDA acknowledged receipt of the IND and assigned the IND number 20486. As this IND was inactivated by Eli Lilly and Company via letters to the FDA dated September 26 and October 25, 1990, and is unrelied upon in the present

application, applicant asserts that this first IND is irrelevant to the present request for patent term extension.

(14) The prescribed fee for receiving and acting upon the application for extension (See §1.20(j)):

As indicated by the letter of transmittal submitted with this application, the Assistant Commissioner for Patents has been authorized to charge the filing fee of $1,120.00 to deposit account No. 05-0840 in the name of Eli Lilly and Company and any additional fees which may be required.

(15) The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed:

Address all correspondence to James J. Sales, Eli Lilly and Company, Patent Division/JJS, Lilly Corporate Center, Indianapolis, Indiana 46285. Direct telephone calls to James J. Sales, 317-276-3474.

(16) A duplicate of the application papers, certified as such:

The undersigned hereby certifies that this application for extension of patent term under 35 U.S.C. 156, including its attachments and supporting papers, is being submitted with a duplicate copy thereof.

(17) An oath or declaration as set forth in 37 C.F.R. 1.740(b):

As the undersigned agent of Eli Lilly and Company, the owner of record of U.S. Patent No. 4,418,068, which, by submission of this paper and attached Exhibits, now applies for an extension of term of this patent, I, David E. Boone, declare that (1) I am a Patent Attorney authorized to practice before the Patent and Trademark Office and have general authority from Eli Lilly and Company to act on its behalf in patent matters; that (2) I have reviewed and understand the contents of this application for extension of U.S. Patent No. 4,418,068; that (3) I believe the patent is subject to extension pursuant to 37 C.F.R. 1.710; that (4) I believe the length of extension claimed is fully justified under 35 U.S.C. 156 and applicable regulations; and that (5) I believe the patent for which this extension is being sought meets the

conditions for extension of the term of a patent as set forth in 37 C.F.R. 1.720.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent extension issuing thereon.

I hereby appoint as United States attorneys to prosecute this request and to transact all business in the Patent and Trademark Office connected therewith: David E. Boone, Reg. No. 27,857, Robert A. Conrad, Reg. No. 32,089, and James J. Sales, said David E. Boone, Reg. No. 27,857 to have in addition full power of revocation, including the power to revoke the power herein granted to said Robert A. Conrad and James J. Sales.

ELI LILLY AND COMPANY

By: _____

David E. Boone
Assistant Secretary
Deputy General Counsel
General Patent Counsel
Registration No. 27,857
Phone: 317-276-3881

Eli Lilly and Company
Patent Division/JJS
Lilly Corporate Center
Indianapolis, Indiana 46285

Jan. 20, 1998